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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PHILLIP D. FREEDMAN ATTORNEY AT LAW 6000 WESCOTT HILLS WAY ALEXANDRIA, VA 22315-4747				
EXAMINER MAHATAN, CHANNING				
ART UNIT		PAPER NUMBER		
1631				

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/595,005

Applicant(s)

CAWSE ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15-27, 30-33, 40 and 42-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-27, 30-33, 40 and 42-79 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### *APPLICANTS' ARGUMENTS*

Applicants' arguments filed 24 October 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-12, 15-27, 30-33, 40, and 42-79. Claims 13, 14, 28, 29, 34-39, and 41 have been cancelled.

### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### *NEW MATTER*

Claims 22-27, 30-33, 40, 42-79 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 22, 40, 61, and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The introduction of "favorable catalytic properties"/"favorable properties" and the addition of new claims 42-79 is considered new matter.

Applicants state the following for support of amendments and new claims 42-79:

"New claim 61 and its dependent claims are based on dependent claims 13 and 14, the specification page 7, lines 13 to 14 and the Examples. Similarly, the amendments to claim 22 is based on claim 29, which was indicated to be allowable over the art. The new claims 42 to 60 are based on claims already in the case."

This is incorrect since there did not appear any disclosure or contemplation of "favorable catalytic properties"/"favorable properties" in the specification. The original disclosure states the following with regard to property used for evaluation:

"Step 26 determines a property that can be used to evaluate each entity of the first population.

For example, the property may be effectiveness as a catalyst or flame retardant or toxicity or rate of production or yield of a set of reaction parameters or any property of interest." (page 10, lines 17-20 of the Specification).

"Step 34 determines the same property for the second population as was determined and used to evaluate each entity of the first population." (page 11, lines 16-18 of the Specification)

The above sections from the original disclosure provide only a small list of properties to be evaluated, whereas the amended claims broadly encompass any property (i.e. catalytic bond formation, pH, activation energy, etc). Further, absent is an indication if any these example properties (above) are considered favorable (Refer to below 35 U.S.C. § 112 2<sup>nd</sup> Paragraph Rejection) and the condition(s)/value(s) (i.e. threshold) that would satisfy the criteria of being considered favorable. Therefore, the introduction of "favorable catalytic properties" and newly added claims 42-79 is considered NEW MATTER.

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**Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 15-27, 30-33, 40, and 42-79 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*VAGUE AND INDEFINITE*

Claim 1 and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is "A method to identify improved catalytic mixture entities", however, instant claim 1 recites a final step of "(B) executing a genetic algorithm based on said property of said entities to identify a second population of entities". There is no indication "improved catalytic mixture entities" are identified. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when "improved catalytic entities" are identified. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claims 1, 4-11, 22, 23, 26, 40, 44-52, 61, 64-72, and all claims dependent therefrom recite the phrase "a second population of entities"/"a third population of entities" which is vague and indefinite. Applicants cite McGraw-Hill Dictionary of Scientific and Technical Terms, 5<sup>th</sup> Ed., p 1548 (1994) for the definition of "population" as "[a] specified set of objects or outcomes to be measured or observed" and then cites Merriam Webster's Collegiate Dictionary, 10<sup>th</sup> Ed., page 387 (1993) for the definition of "entity" which is stated to be "something that has separate

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and distinct existence and objective or conceptual reality.” It is unclear what distinguishes the “first population of entities” from the “second population of entities” from the “third population of entities” since the above definitions state a “specified set of objects or outcomes to be measured” which are “separate and distinct”. If it is Applicants intent that “favorable catalytic properties”/“favorable properties” distinguishes the population(s) said “favorable catalytic properties”/“favorable properties” are unclear (Refer to above 35 U.S.C. § 112 2<sup>nd</sup> Paragraph Rejection). Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 12, 52, and 72 recites the phrase “a fit entity” which is vague and indefinite. Applicants cite Merriam Webster’s Collegiate Dictionary, 10<sup>th</sup> Ed., page 387 (1993) for the definition of “entity” which is stated to be “something that has separate and distinct existence and objective or conceptual reality” and then cites McGraw-Hill Dictionary of Scientific and Technical Terms, 5<sup>th</sup> Ed., p 1548 (1994) for the definition of “fitness” which is stated to be “a measure of reproductive success”. Applicants definition supports the Examiners assertion that the phrase “a fit entity” implies an entity (i.e. separate and distinct) is “fit” based upon some criteria (i.e. measure of reproductive success), however, such a criteria of reproductive success is unclear. Applicants can resolve this issue by particularly pointing out what establishes reproductive success and thus is considered “a fit entity”.

Claim 22 and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is “A high throughput screening (HTS) method to identify entities of an improved catalyst system”, however, instant claim 22 recites a final step of “(D) executing a genetic algorithm based on said property of said plurality of products to identify a second

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population of entities with favorable catalytic properties". There is no indication "entities of an improved catalytic system" are identified. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when "entities of an improved catalytic system" are identified. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claim 22 (line 9), claim 40 (lines 6-7), claim 61 (line 11), and all claims dependent therefrom recite the limitation "favorable catalytic properties"/"favorable properties" which is vague and indefinite. It is unclear what Applicants' regard as favorable. Applicants can resolve this issue by particularly pointing out what is considered favorable. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 61 and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is "A method to identify improved mixture entities", however, instant claim 61 recites a final step of "(B) executing a genetic algorithm based on said property of said entities to identify a second population of entities with favorable properties". There is no indication "improved mixture entities" are identified. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when "improved catalytic entities" are identified. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

### **Claims Rejected Under 35 U.S.C. § 102**

The rejection of claims 1-12 under 35 U.S.C. § 102(b) as being anticipated by Singh et al. is maintained for reasons of record.

Applicants' argue Singh et al. does not teach or suggest (1) "forming catalytic mixture entities" and (2) "detecting a catalytic property of each of said mixture entities". Applicants' argument is found unpersuasive and is addressed below.

Singh et al. prepares catalytic mixture entities, which are formed when the peptides are tested for fluorescence with a stromelysin protease array (i.e. catalytic mixture entity is peptide plus stromelysin protease). The detection of fluorescence indicates the amount of catalytic activity (i.e. catalytic property) of the stromelysin protease with the peptide (Figure 2, and Scheme 3). Singh et al. implements and summarizes (Scheme 3) the described method to an initial random population, synthesizes said first population, determines the fitness of the first population, executes the modified genetic algorithm, repeats the method for 5 generations, and identifies active samples; wherein the method would generated several generations of populations (i.e. third population) and the final generation being the identified fit entities (page 1671, left and right columns, lines 18-55 and 1-46, respectively). As written, the catalytic mixture entities of the claims include those mixture entities taught by Singh et al. Thus, Singh et al. anticipates the claimed invention.

#### *OBJECTION TO CLAIMS*

Claim 2 remains objected to because of a typographical error wherein the claim contains inconsistent Roman numerals: "... (i) mutation, (ii) crossover, (III) mutation and selection (iv)



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crossover and selection and (v) mutation, crossover and selection.” Appropriate correction is requested.

*ACTION IS FINAL, AS NECESSITATED BY AMENDMENT*

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**No Claims Are Allowed.**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380 (until 12 January 2004) and (571) 272-0717 (after 12 January 2004). The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

*January 8, 2004*

Examiner Initials:

*GSM*

*Marianne P. Allen*  
MARIANNE P.  
PRIMARY EXAMINER  
*AU1631*